

William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

VALEANT PHARMACEUTICALS
NORTH AMERICA LLC; VALEANT
PHARMACEUTICALS IRELAND LTD.;
DOW PHARMACEUTICAL SCIENCES, INC.;
and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

STRIDES PHARMA INC. and
STRIDES PHARMA GLOBAL PTE LTD.,

Defendants.

Civil Action No. 19-00133

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals North America LLC (“Valeant”), Valeant Pharmaceuticals Ireland Ltd. (“Valeant Ireland”), Dow Pharmaceutical Sciences, Inc. (“Dow”), and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Strides Pharma Inc. (“Strides USA”) and Strides Pharma Global PTE Ltd. (“Strides Global”) (collectively, “Strides” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Valeant Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Dow is a corporation organized and existing under the laws of Delaware having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Strides USA is a New Jersey corporation having a principal place of business at 2 Tower Centre Blvd, Suite 1102, East Brunswick, NJ 08816.

6. Upon information and belief, Strides Global is a Singapore corporation having a principal place of business at 8 Eu Tong Sen Street, #15-93, The Central, Singapore, 059818.

7. Upon information and belief, Strides USA is authorized to act on behalf of Strides Global.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent No. 10,105,444 (“the ‘444 Patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Strides’ filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”)

approval to market its generic efinaconazole topical solution, 10% (“Strides’ generic efinaconazole topical solution”).¹

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

10. Upon information and belief, this Court has jurisdiction over Strides USA. Upon information and belief, Strides USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Strides USA directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Strides USA’s generic efinaconazole topical solution. Upon information and belief, Strides USA is a New Jersey corporation having a principal place of business at 2 Tower Centre Blvd, Suite 1102, East Brunswick, NJ 08816. Upon information and belief, Strides USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Strides USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

11. Strides USA has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere.

¹ Plaintiffs previously brought an action for infringement of United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”), and 9,877,955 (“the ’955 patent”). That action is currently pending in this Court as Case No. 3:18-cv-13696 (PGS) (LHG), and Plaintiffs hereby incorporate by reference their Complaint against Strides (ECF No. 1) in that action.

Strides USA's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Strides USA intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Strides USA will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

12. Upon information and belief, this court has jurisdiction over Strides Global. Upon information and belief, Strides Global is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Strides Global directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Strides' generic efinaconazole topical solution. Upon information and belief, Strides Global purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Strides Global has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Strides knows or should know that Jublia[®] is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Jublia[®].

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

15. Venue is proper against Strides USA because it is incorporated in New Jersey operates a principal place of business in this judicial district.

16. Venue is proper against Strides Global, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENT IN SUIT

17. The United States Patent and Trademark Office (“PTO”) issued the ’444 patent on October 23, 2018. The ’444 patent claims, generally speaking, *inter alia*, pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and antioxidant. Plaintiffs hold all substantial rights in the ’444 patent and have the right to sue for infringement thereof. The ’444 patent is valid and enforceable. A copy of the ’444 patent is attached hereto as Exhibit A.

18. Dow is the holder of New Drug Application (“NDA”) No. 203567 for Jublia[®], which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the ’444 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

19. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia[®].

STRIDES’ INFRINGING ANDA SUBMISSION

20. Upon information and belief, Strides USA, on behalf of Strides Global, filed or caused to be filed with the FDA ANDA No. 211985, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

21. Upon information and belief, Strides USA’s ANDA No. 211985 seeks FDA approval to sell in the United States Strides’ generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

22. Dow received a letter dated November 21, 2018 from Strides USA purporting to

be a Notice of Certification for ANDA No. 211985 (“Strides’ notice letter”) under Section 505(j)(2)(B)(ii) and (iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii) and (iv), and 21 § C.F.R. 314.95(c) that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

23. Strides’ notice letter alleges that Strides USA has submitted to the FDA ANDA No. 211985 seeking FDA approval to sell Strides’ generic efinaconazole topical solution, intended to be a generic version of Jublia®.

24. Upon information and belief, ANDA No. 211985 seeks approval of Strides’ generic efinaconazole topical solution that is the same, or substantially the same, as Jublia®.

COUNT I AGAINST STRIDES

Infringement of the ’444 Patent under § 271(e)(2)

25. Paragraphs 1-24 are incorporated herein as set forth above.

26. Under 35 U.S.C. § 271(e)(2), Strides has infringed at least one claim of the ’444 patent by submitting, or causing to be submitted to the FDA, ANDA No. 211985 seeking approval for the commercial marketing of Strides’ generic efinaconazole topical solution before the expiration date of the ’444 patent.

27. Upon information and belief, Strides’ generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the ’444 patent.

28. Upon information and belief, Strides will, through the manufacture, use, import, offer for sale, and/or sale of Strides’ generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’444 patent.

29. If Strides’ marketing and sale of its generic efinaconazole topical solution prior to the expiration of the ’444 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST STRIDES

Declaratory Judgment of Infringement of the '444 Patent

30. Paragraphs 1-29 are incorporated herein as set forth above.

31. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

32. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

33. Strides has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Strides' generic efinaconazole topical solution before the expiration date of the '444 patent, including Strides' filing of ANDA No. 211985.

34. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Strides' generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '444 patent.

35. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Strides' generic efinaconazole topical solution will constitute infringement of at least one claim of the '444 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Strides on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Strides has infringed at least

one claim of the '444 patent by submitting or causing to be submitted ANDA No. 211985 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Strides' generic efinaconazole topical solution before the expiration of the '444 patent;

2. order that that the effective date of any approval by the FDA of Strides' generic efinaconazole topical solution be a date that is not earlier than the expiration of the '444 patent, or such later date as the Court may determine;

3. enjoin Strides from the commercial manufacture, use, import, offer for sale, and/or sale of Strides' generic efinaconazole topical solution until expiration of the '444 patent, or such later date as the Court may determine;

4. enjoin Strides and all persons acting in concert with Strides from seeking, obtaining, or maintaining approval of Strides' ANDA No. 211985 until expiration of the '444 patent;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: January 4, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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Charles H. Chevalier

J. Brugh Lower

GIBBONS P.C.

One Gateway Center

Newark, New Jersey 07102

Tel: (973) 596-4500

Fax: (973) 596-0545

wdeni@gibbonslaw.com

cchevalier@gibbonslaw.com

jlower@gibbonslaw.com

Attorneys for Plaintiffs

Of Counsel:

Thomas P. Steindler (*pro hac vice* to be submitted)

Nicole M. Jantzi (*pro hac vice* to be submitted)

Paul M. Schoenhard (*pro hac vice* to be submitted)

Ian B. Brooks (*pro hac vice* to be submitted)

MCDERMOTT WILL & EMERY LLP

The McDermott Building

500 North Capitol Street, NW

Washington, DC 20001-1531

(202) 756-8000

Attorneys for Plaintiffs

Valeant Pharmaceuticals North America LLC,

Valeant Pharmaceuticals Ireland Ltd., and

Dow Pharmaceutical Sciences, Inc.

John D. Livingstone (*pro hac vice* to be submitted)

FINNEGAN, HENDERSON,

FARABOW, GARRETT & DUNNER, LLP

271 17th Street, NW

Suite 1400

Atlanta, GA 30363-6209

(404) 653-6400

Naoki Yoshida (*pro hac vice* to be submitted)

FINNEGAN, HENDERSON,

FARABOW, GARRETT & DUNNER, LLP

33rd Floor, Shiroshima Trust Tower

3-1, Toranomom 4-chome, Minato-ku

Tokyo, 105-6033 Japan
+81-3-3431-6943

Attorneys for Plaintiff
Kaken Pharmaceutical Co., Ltd.

CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 4, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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